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MAR 20 2009

Jeffrey P. Kushan
Sidley Austin LLP
1501 K Street NW
Washington DC 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,639,055

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 6,639,055, claims of which cover the human biologic drug product AVASTIN® (bevacizumab), and the claims of which cover a method that may be used to make or use AVASTIN® (bevacizumab), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 121 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 6,054,297 based on the regulatory review period for the human drug product AVASTIN® (bevacizumab).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension relating to the above captioned patent, U.S. Patent No. 6,639,055, will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 6,054,297. In the absence of a request for reconsideration, and if U.S. Patent No. 6,639,055 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 121 days in U.S. Patent No. 6,639,055.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 20, 2006, and May 14, 2008 (71 Fed. Reg. 54997 and 73 Fed. Reg. 27836). Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (2,401 - 2,401) + (150 -29) days
	=	121 days (0.3 years)

Since the regulatory review period began March 5, 1997, before the patent issued (October 28, 2003), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From March 5, 1997, to and including, October 28, 2003, is 2,401 days in the testing phase and 29 days in the approval phase; these periods are subtracted for the number of days occurring in the testing phase and approval phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,639,055
Granted:	October 28, 2003
Original Expiration Date[1]:	July 18, 2011
Applicant:	Paul J. Carter, et al.
Owner of Record:	Genentech, Inc.
Title:	Method for Making Humanized Antibodies
Product Trade Name:	AVASTIN® (bevacizumab)
Term Extended:	121 days
Expiration Date of Extension:	November 16, 2011

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: AVASTIN® (bevacizumab)
Docket No.: FDA-2004-E-0519